

# Exhibit 44

## Alternative Extrusion Grade Resins For PEEK

6/94

L. Wasicek

### Objective:

To determine if there is a commercially available extrusion grade resin which would give us a better performing proximal shaft than the Victrex PEEK material (grade 381G).

### Background/History:

In January of 1994, there was a brain storming meeting regarding alternative technologies to the Elastinite IM. Elastinite was estimated at \$25-35 per tube/catheter. At this point in time, there was a heavy concern with the high cost of Elastinite and that it would not be a viable design option. Also, the thoughts were the market would be very cost sensitive in 1995-1996 and catheter prices would be around \$400/catheter. We already started investigating PEEK as a proximal stiff shaft as a Elastinite IM replacement. The idea came up to investigate other advanced polymers such as engineering resins as shaft materials and determine the best one.

### Research Procedures:

- Held brain storming meeting regarding Elastinite replacement. See memo dated 1/14/94.
- Research high modulus extrusion grade polymers. Reference article in Modern Plastics (Nov. 1993) titled, Advanced Thermoplastics Electronics Markets Hum Along While Military and Aerospace Falter
- Call vendors and obtain material property data information.
- Compile spreadsheet with material property data. (see attached)
- Held meeting and selected resins to investigate (see memo dated 3/2/94).

#### Selection Criteria:

Very high modulus

Low moisture absorption < 1.6%

Elongation > 50%

- Order resins.
- Extrude resins.
- Evaluate and test materials

### Distribution:

J. Lee

D. Cox

B. Ainsworth

E. Leopold

S. Schauble

cc: J. Becker

**Materials:****High Temperature Engineering Resins:**

Polyetheretherketone (PEEK)  
Polyethersulfone (PES)  
Polyphenylenesulfide (PPS)  
Polyaryletherketone (PAEK)

**Extrusion Run Numbers:**

Acutech (outside vendor)  
#10-576-1  
#10-556  
N/A

**Other Resins Included In The Analysis:**

EVAL	12-142
Pebax 7233	11-223
Nylon 12	11-221
Isoplast	10-531-1
*Hytrel	N/A
PET	11-219-1

\*Note: Hytrel was extruded but testing was stopped due to vendor agreement problems.

**Tests:**

- Tinius Olson Slope: This is the slope using angles 0,3,6,9.
- Tinius Olson Kink: Record the peak load value before it kinks and loses its strength.
- Circle Kink: Put the tubing in a circle and continue to decrease the circle size while matching it to a circle template. Record the smallest circle the material would fit before kinking. This test should be used for reference only.
- Rupture pressure: Record the average rupture pressure.
- Mechanical: Modulus, elongation, and strength. Testing completed at ACS at room temperature.

**Acceptance Criteria:**

Tinius Olson Slope: Catheter having the highest number is considered the best.

Tinius Kink: Catheter having the highest number is considered the best.

Circle Kink: Reference information only.

Rupture Pressure: Catheter must be able to withstand a minimum of 350 psi. (Protocol located in E. Williams lab notebook)

Modulus & Strength: Having a high modulus & strength is considered having better stiffness for the shaft performance.

Elongation: This material property is best correlated with post processing operations. For now, tubing should have a minimum elongation of at least 50%. This number is based on the post processing conditions from prior experiments using in-house and Accutech PEEK extrusions.

**Results:**

See attached spreadsheets.

## **Conclusion:**

### **Material Summary - Compared to PEEK:**

#### **PEEK:**

This material has the highest modulus (408-428kpsi), strength (15.3-16.2 kpsi), Tinius Olson slope (4.28) & kink angle (79 degrees). It also has a rupture pressure over 500psi with an elongation of 56-69%. In my opinion this is the best material of all the materials tested.

#### **PES**

Compared to PEEK this material does not have as high a modulus (408-428 kpsi vs 323kpsi). Tinius Olson slope is 2.21 compared to PEEK at 4.27 and the T/O kink angle is 45 degrees compared to PEEK's 79 degrees. This material has adequate rupture pressure at 500psi, plenty of elongation at 150%. It has a strength value of 15,200 psi compared to PEEK 15,300 - 16,200 psi.

#### **PPS:**

Compared to PEEK this material does not have as high a modulus (408-428kpsi vs 297 kpsi). Tinius Olson slope is 2.63 compared to PEEK at 4.27 and the T/O kink angle is 44 degrees compared to PEEK's 79 degrees. Rupture pressure is OK at 411 psi. Elongation at 335% is acceptable. It has a strength value of 10,700 psi compared to PEEK 15,300-16,200 psi.

#### **Pebax:**

This material has a poor Tinius Olson slope of .71 and a T/O kink angle of 17 degrees. The modulus was approximately 1/4 that of PEEK at 104 kpsi. Rupture pressure was adequate at 411 psi along with an elongation of 285%. It's strength compared to PEEK is 10,900 psi vs 15,300-16,200

#### **Isoplast:**

Compared to PEEK this material does not have as high a modulus (408-428 kpsi vs 314 kpsi). Tinius Olson slope is 3.01 compared to PEEK at 4.27 and the T/O kink angle is 59 degrees compared to PEEK's 79 degrees. Rupture pressure is OK at 387 psi. Elongation at 130% is acceptable. It has a strength value of 13,900 psi compared to PEEK 15,300 - 16,200 psi.

PET: Compared to PEEK this material does not have as high a modulus (408-428 kpsi vs 311 kpsi). Tinus Olson slope is 1.76 compared to PEEK at 4.27 and the T/O kink angle is 31 degrees compared to PEEK's 79 degrees. Rupture pressure is at 500+ psi. Elongation at 698% is acceptable. It has a strength value of 13,600 psi compared to PEEK 15,300 - 16,200 psi.

Nylon 12:

This material had a average rupture of 291 psi which is unacceptable. See spreadsheets for additional information

EVAL:

This materials has an unacceptable rupture pressure. When material came in contact with water at 37c it became very supple( noodle-like). Because of these results this material is found to be unacceptable. See spreadsheets for additional information

PAEK:

There were 3-4 attempts to extrude tubing and because of difficulties no tubing was obtained.

#### **Recommendation:**

Continue PEEK development efforts for the Next Generation .014" O-T-W. Continue in-house development efforts along with procuring material from Accutech. All materials tested do not have the performance that is comparable to PEEK. With regard to PEEK improvements, the only improvement that I can foresee would be to increase the elongation properties to improve post processing conditions. Optimizing the PEEK extrusion will start in June 1994 with Steve Schaible completing a DOE for extrusion conditions.

PAEK should be investigated at a later time.

#### **Miscellaneous:**

Material information for rupture data can be located in Eric William's lab notebook.

For information regarding the mechanical properties see Ted Slater in the Materials Department.

Additional information can be found in Larry Wasicek's lab notebook

# Material Properties

Information From Manufacture Property Data Sheet										
Test Method	Name/Grade	ASTM D638 Ten. @ Yield	ASTM D638 Ten. @ Break	Tensile Mod	ASTM D638 Elong. @ Yld	Ultimate Elong.	ASTM D790 Flex. Mod.	ASTM D570 Moist. Absb.	Rockwell	Comments
Units		PSI	KPSI	KPSI	Percent	Percent	KPSI	Percent	Hardness	
Advanced Resin:									Scale	
Polyetheretherketone (PEEK)	Victrax 381	N/A	13.5	N/A	4.9	50	594	0.50	N/A	
Polysulfone (PSF)	Udel-P3500	N/A	10.2	360	N/A	50-100	390	0.30	N/A	
Polysulfone (PSF)	Ultrason-S3010	11500	N/A	N/A	5.7	60-85	370	0.80	M-69	Mod. Elast. 390 kpsi
Polyethersulfone (PES)	Ultrason-E3000	13000	N/A	N/A	6.7	15-40	370	2.10	M-85	Mod. Elast. 410 kpsi
Polyethersulfone (PES)	Radel-R5000	N/A	10.1	340	7.2	80-120	350	0.37	N/A	
Polyethersulfone (PPSU)	Radel-A200	N/A	12	385	6.5	N/A	420	1.85	N/A	
Polyetherimide (PEI)	Ultem 1000	N/A	14.5	420	N/A	70	450	0.16	R-123	From J. Lee
Polyphenylenesulfide (PPS)	Forton	N/A	12.5	N/A	4.5	N/A	600	0.01	M-93	
Polyaryletherketone (PAEK)	Ultrapek A-3000	17110	N/A	N/A	5.2	N/A	N/A	0.80	D-86	Y. Mod. 580 kpsi
Polyphenylenesulfide (PPS)	Rayton	glass filled only								
Polyphthalamide (PPA)	AMODEL	glass filled only								
Resin:										
EVAL	L101	13655	10.4	455	N/A	200	N/A	N/A	N/A	From J. Lee
EVAL	H101A	9385	6.7	341	N/A	280	N/A	N/A	N/A	From J. Lee
EVAL	E105A	8535	7.4	299	N/A	280	N/A	N/A	N/A	From J. Lee
Pebax	1147	N/A	9.1	N/A	N/A	N/A	133	N/A	N/A	
Phillips	Resin KR03	3700	N/A	N/A	N/A	160	205	0.09	Shore 65D	

Room Temperature Data							
Material	Extrusion #	Type	Tensile			Compression	
			Strength (psi)	Elongation (%)	Modulus (psi)	Modulus (psi)	E <sup>1</sup> (lbs * in <sup>2</sup> )
PEEK	Acutech	OM	15,300	56%	408,000	149,000	3.63E-03
PEEK	Acutech	OM	16,200	69%	428,000	N/A	#N/A
PES	10-576-1	OM	15,200	150%	323,000	175,000	#N/A
PPS	10-556-1	OM	10,700	335%	297	147,000	#N/A
EVAL	12-142-A	OM	N/A	N/A	N/A	N/A	#N/A
EVAL	12-142-A Irrad.	OM	N/A	N/A	N/A	N/A	#N/A
NYLON 12	11-221-1?	OM	9,360	206%	144,000	79,000	1.65E-03
PET	11-219-1	OM	13,600	698%	311,000	138,000	3.14E-03
IsoPlast	10-531-1	OM	13,900	130%	314,000	131,000	3.05E-03
Pebax	10-560-1	OM	10,900	285%	104,00	52,400	
PAEK	Unable to extrude						#N/A

# Test Results

Test Results - Data Sheet						
Test Method	Tinius Olson		Kink Angle Radius		Rupture Pressure	Kink & Pull
Units	Slope	Kink Angle	Inches	PSI	Comments	
<b>Advanced Resin:</b>						
Polyetheretherketone (PEEK)	4.27	79	9/16"	500+	GD	
Polyethersulfone (PES)	2.21	45	1/2"	500+	GD	
Polyphenylenesulfide (PPS)	2.63	44	7/8"	411	GD	
Polyaryletherketone (PAEK)	N/A	N/A	N/A	N/A	N/A	
EVAL	N/A	N/A	5/8"	123	OK	
Pebax	0.71	17	7/16"	411	GD	
Isoplast	3.01	59	15/32"	387	Separates easily	
Nylon 12	1.04	24	1/2"	291	GD	
PET	1.76	30	3/4"	500+	GD	
Sample Size	3	3	2	5	2	